

SPRING VIRTUAL EVENT

PCC

Pharmaceutical Compliance Congress



Earn CLE and
CPE credits*

*PENDING FINAL APPROVAL

APRIL 27-29, 2021

THE WORLD'S LEADING BIO/PHARMA EVENT FOR COMPLIANCE AND LEGAL PROFESSIONALS

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CHRISTIE CAMELIO

Chief Compliance, Ethics and
Risk Management Officer,
TG Therapeutics



ADAM DUBOW

Chief Compliance
and Ethics Officer,
Bristol Myers Squibb



BETH HOLLY

Senior Vice President, Associate General
Counsel & Chief Compliance Officer,
Regeneron Pharmaceuticals



RACHAEL HONIG

Acting U.S. Attorney,
U.S. Attorney's Office for the
District of New Jersey



ANDREW LELLING

U.S. Attorney,
U.S. Attorney's Office for the
District of Massachusetts



JILL FALLOWS MACALUSO

Corporate Vice President, North America,
Chief Ethics, Compliance and Privacy Officer,
Novo Nordisk



GREGORY MOSS

Executive Vice President, General
Counsel and Corporate Secretary,
Chief Compliance Officer,
Kadmon



ANDY RITTENBERG

Senior Vice President Legal
and Chief Compliance Officer,
Gilead Sciences



ANN-MARIE TEJCEK

Senior Director, Chief Compliance
Officer, North America,
Eli Lilly and Company



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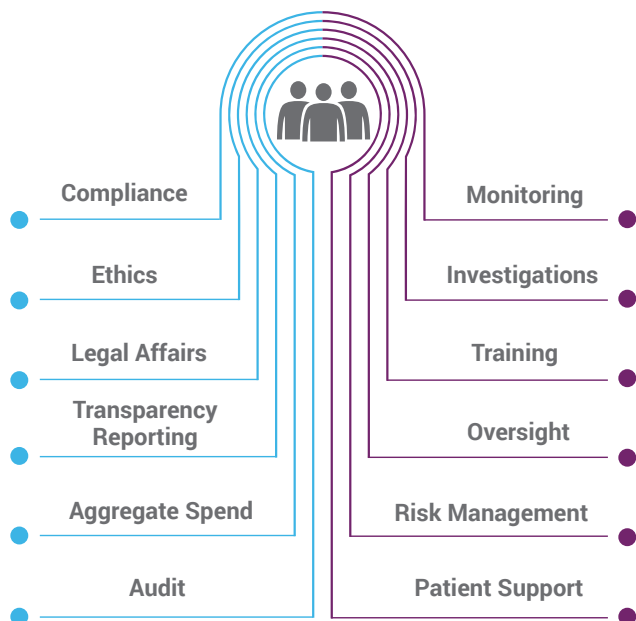


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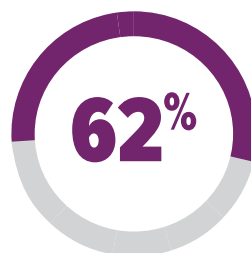
#PCC2021

PCC is the Premier Conference for Staying on the Pulse of Enforcement Trends, Supercharging Your Best Practice Playbook and Expanding Your Network

WHO ATTENDS



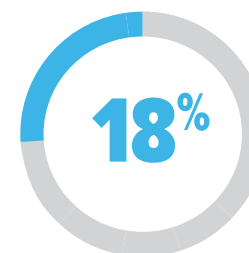
80% OF LIFE SCIENCES PARTICIPANTS HAVE DISTINCT FUNCTIONAL EXPERTISE



**Compliance/
Ethics/Oversight**

KEY TITLES NOTED:

- CCO
- SVP Compliance & Privacy Officer
- Sr Director, Ethics & Business Integrity
- Global Chief Compliance Officer
- SVP, Chief Compliance & Risk Officer
- Sr Director, Compliance Monitoring

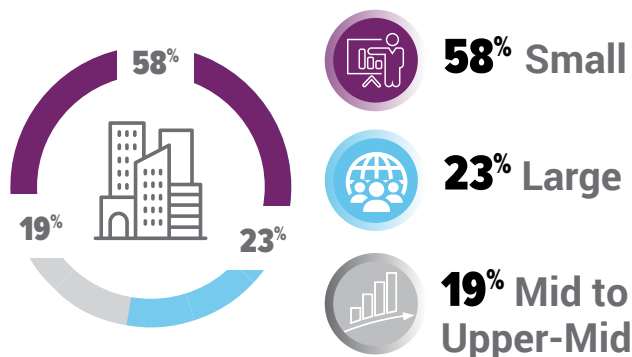


**Legal
Affairs**

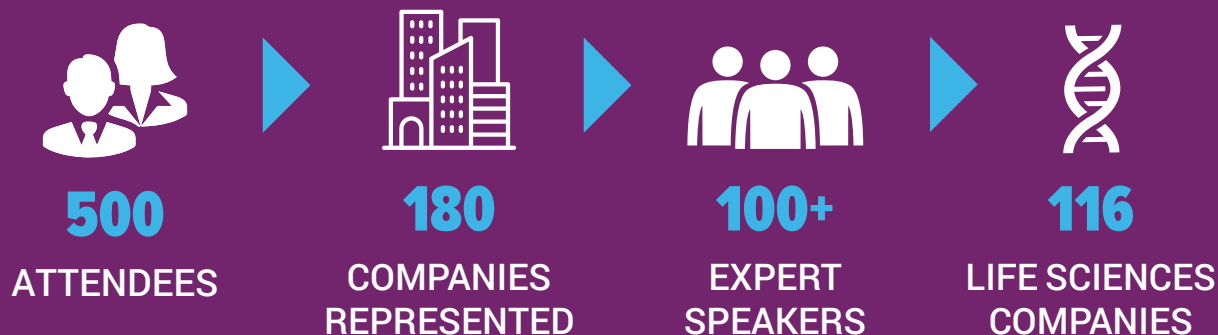
KEY TITLES NOTED:

- General Counsel
- Exec VP, GC & Corporate Secretary
- Legal Counsel IP & Contracts
- Global Life Sciences Attorney
- VP, U.S. Legal Affairs & General Counsel
- Exec Director, Head U.S. Legal Bus. Services

COMPANY TYPE



PCC PAST PARTICIPANT PROFILE



Held during the long-standing April timeframe, PCC Spring Virtual Event provides progressive insights from the world's most experienced compliance and legal professionals on the issues that matter for 2021. Delivered in an all-digital format, hear critical policy, regulatory and enforcement updates, benchmark winning frameworks and collaborate on best practices for compliance excellence in the year ahead.

Gain Access to a Combination of Live Sessions, On-Demand Content, Synchronous Learning and Networking



Benefit from live expert panels and presentations, with polling and real-time Q&A



Participate in interactive round tables and smaller group learning/networking



Access on-demand/recorded sessions at the convenience of your schedule over a 30-day viewing window



Earn CLE/CPE credits*
(pending final approval)



Gain virtual access to the Sponsorship Pavilion and take part in VIP meeting matchmaking



Take advantage of elevated and direct access to thought-leaders and experts

PCC VIRTUAL ATTENDEE ACCLAIM:

"Very informative and well-run Congress!
I would definitely attend again virtually
and in person!"

"PCC 2020 has set the bar again! The congress brought the most timely information about enforcement trends and 'must knows' for compliance professionals to the main stage... and this time that stage was virtual! Thank you for breaking down the physical walls and expanding the access to this critical congress via the virtual format. In my view, I visualized many of the sessions as standing room only. Excellent all around!"



AGENDA

DAY ONE: TUESDAY, APRIL 27, 2021

*Please note all times are listed in EDT

10:15-10:20 AM

LIVE **Informa Connect and Chairperson's Welcome**

Caitlin Murgia, Program Director, **Informa Connect**

Beth Holly, Senior Vice President, Associate General Counsel & Chief Compliance Officer, **Regeneron Pharmaceuticals**

10:20-10:50 AM

LIVE **State of the Industry – Current Snapshot of Affairs Coming Off an Unprecedented and Politically Charged Year**

Jim Stansel, Executive Vice President and General Counsel, **PhRMA**

11:00 AM-12:00 PM

LIVE **Fireside Chat with CCOs – Top Transformation Topics for our Compliance Operating Model in 2021**

MODERATOR:

Bill Buzzee, Vice President and General Manager of the U.S. Compliance Center of Excellence, **IQVIA**

PANELISTS:

Adam Dubow, Chief Compliance and Ethics Officer, **Bristol Myers Squibb**

Jill Fallows Macaluso, Corporate Vice President, North America, Chief Ethics, Compliance and Privacy Officer, **Novo Nordisk**

Andy Rittenberg, Senior Vice President Legal and Chief Compliance Officer, **Gilead Sciences**

Ann-Marie Tejcek, Senior Director, Chief Compliance Officer, North America, **Eli Lilly and Company**

12:00-1:30 PM



TAKE TIME FOR NETWORKING

Visit the Exhibit Booths, Engage with Peers and Tap into the Knowledge Resource Hub of On-Demand Sessions

1:30-2:30 PM

LIVE **Keynote Enforcement Panel on Emerging Trends**

Hear about the most recent and impactful cases impacting bio/pharmaceutical manufacturers.

MODERATOR:

T. Reed Stephens, Partner, **Winston and Strawn LLP**

PANELISTS:

Rachael Honig, Acting U.S. Attorney, **U.S. Attorney's Office for the District of New Jersey**

Nathaniel Mendell, First Assistant U.S. Attorney, **U.S. Attorney's Office for the District of Massachusetts**

Gustav Eyler, Director, Consumer Protection Branch, **U.S. Department of Justice (DOJ)**

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CBI Compliance Series



Tweet your learnings @CBI_Conferences
#PCC2021



3:00-4:00 PM

LIVE Choose from Four Interactive and Engaging Working Groups

Led by industry colleagues, take part in thought-provoking discussions and timely benchmarking on critical topic areas.

WORKING GROUP I

Advancing Digital and Virtual Interactions

Tom Hayes, Director of Offering Management, **IQVIA**

Gail Gillespie, Senior Director, U.S. Commercial Compliance & Ethics, **Teva Pharmaceuticals**

Mike Varlotta, Senior Director, Commercial Operations, **Johnson & Johnson**

WORKING GROUP II

Optimizing Compliant Patient Interactions

Kathy Dourousseau, Chief Compliance Officer, **Rigel Pharmaceuticals**

Andrea Kocharyan, Vice President, Head of Legal and Compliance, **Zealand U.S.**

Meena Datta, Partner, **Sidley Austin LLP**

Daina Selvig, Vice President, Chief Compliance Officer, **Ardelyx**

Marci Juneau, Partner, **Helio Health Group**

WORKING GROUP III

Trends from 2020 Transparency Reporting and Tips for 2021

Chelsea Ott, Regulatory and Compliance, Senior Associate, **MedPro Systems LLC**

Terra Buckley, Vice President, Head of Compliance Advisory Services, **MedPro Systems LLC**

WORKING GROUP IV

Next-Gen Compliance Monitoring

Mohammad Ovais, Founder and CEO, **qordata**

4:00-5:00 PM

LIVE Closed-Door CCO and GC Summit*

The CCO and GC Summit provides world-class thought-leadership and is designed to deliver high-quality information that C-suite leaders can develop into an action plan. Collaborate with your distinguished colleagues to gain valuable insights through an interactive and engaging working group.

FACILITATORS: Fabiana Lacerca-Allen, Senior Vice President Compliance, **Aimmune Therapeutics, a Nestle Health Science company**

Neely Agin, Partner, **Winston & Strawn LLC**

Michael Ace, Interim CCO, **Novartis Pharmaceuticals**

To reserve your seat, email Matt.Hannon@informa.com *Informa Connect reserves the right to qualify participants for this Summit. Attendees must be a CCO, VP or GC and currently employed by a life sciences manufacturer.

4:00-5:00 PM



TAKE TIME FOR NETWORKING

Visit the Exhibit Booths, Engage with Peers and Tap into the Knowledge Resource Hub of On-Demand Sessions

DAY TWO: WEDNESDAY, APRIL 28, 2021

*Please note all times are listed in EDT

9:00-10:00 AM

LIVE Industry-Only Solution Summit

Join this small group, interactive session to learn how Compliance Central — PwC's integrated suite of products — supports HCP / HCO interactions, from strategic planning to fair market value, contracting and through payment processing, transparency reporting and compliance monitoring & analytics.

Hosted By:



LIVE Industry-Only Solution Summit: IQVIA Commercial Compliance — Connected Intelligence in Action

IQVIA has transformed the commercial compliance space with innovative technology, advisory services, and data offerings. Beyond HCP Engagement Management, FMV, and Transparency Reporting, subject matter experts leverage insights to evaluate and manage both current and future risk. With compliance embedded throughout our end-to-end solutions, users are assured that risk is reduced throughout the HCP engagement journey and that downstream reporting is accurate and timely. Join IQVIA experts, and see firsthand how our combination of technology, services and data transforms decision-making—enabling compliant interactions, while enhancing user experience. Discover how connected intelligence unleashes the power of data and compliance, delivering ultimate business value.

Bill Buzzee, General Manager, U.S. Compliance & Quality Center of Excellence, **IQVIA**

Dan Spiteri, Senior Director, Transparency Reporting Platform, **IQVIA Commercial Compliance**

Raj Patel, Senior Director, HCP Engagement Platform, **IQVIA Commercial Compliance**

Justin Will, Senior Principal, Global Commercial Compliance Consulting, **IQVIA**

Hosted By:



10:15-10:25 AM	LIVE Day Two Kick-Off – Year in Review Video Reveal Presented By: 	
10:30-11:00 AM	LIVE Analysis of OIG Special Fraud Alert on Speaker Programs and Assessment of Future Activities <i>Tim Robinson, Chief Legal and Privacy Officer, MediSpend</i> <i>Lauren Howe, Compliance Attorney, MediSpend</i>	
11:05-11:30 AM	REGULATORY SHOWCASE LIVE FDA Address <i>Catherine (Katie) Gray, PharmD, Acting Director, Office of Prescription Drug Promotion (OPDP), U.S. Food and Drug Administration (FDA)</i>	
11:30 AM-12:00 PM	LIVE CMS Address <i>Veronika Peleshchuk Fradlin, Director, Division of Transparency Projects, Centers for Medicare & Medicaid Services (CMS)</i>	
12:00-1:00 PM	LIVE Industry-Only Solution Summit <p>Join this small group, interactive session to learn how Compliance Central – PwC’s integrated suite of products – supports HCP / HCO interactions, from strategic planning to fair market value, contracting and through payment processing, transparency reporting and compliance monitoring & analytics.</p> <p>Hosted By: </p>	LIVE Industry-Only Solution Summit: IQVIA Commercial Compliance – Connected Intelligence in Action <p>IQVIA has transformed the commercial compliance space with innovative technology, advisory services, and data offerings. Beyond HCP Engagement Management, FMV, and Transparency Reporting, subject matter experts leverage insights to evaluate and manage both current and future risk. With compliance embedded throughout our end-to-end solutions, users are assured that risk is reduced throughout the HCP engagement journey and that downstream reporting is accurate and timely. Join IQVIA experts, and see firsthand how our combination of technology, services and data transforms decision-making—enabling compliant interactions, while enhancing user experience. Discover how connected intelligence unleashes the power of data and compliance, delivering ultimate business value.</p> <p><i>Bill Buzzee, General Manager, U.S. Compliance & Quality Center of Excellence, IQVIA</i> <i>Dan Spiteri, Senior Director, Transparency Reporting Platform, IQVIA Commercial Compliance</i> <i>Raj Patel, Senior Director, HCP Engagement Platform, IQVIA Commercial Compliance</i> <i>Justin Will, Senior Principal, Global Commercial Compliance Consulting, IQVIA</i></p> <p>Hosted By: </p>
1:00-1:30 PM	Applying Behavioral Science for Impact and to Drive Ethical Culture <ul style="list-style-type: none"> • Learn how sub-conscious cognitive biases often impact employee behavior and how failing to address these biases could result in risk to your company or threatened performance • Understand how recognition of cognitive biases could positively influence ethical decision-making • Participate in an interactive dialogue using specific examples in pharma compliance to illustrate tangible ways to navigate unconscious biases and to be more effective • Realize how the compliance function is uniquely positioned to tailor and measure behavioral interventions intended to foster compliance <p><i>Michael L. Shaw, Principal & Global Head of Risk & Compliance, ZS Associates</i> <i>Jacob Braude, Principal & Head of Applied Behavioral Insights, ZS Associates</i></p>	

1:40-2:40 PM

LIVE **Former Prosecutor Panel – Answers and Insights from Industry’s Trusted Advisors**

During this thought-provoking discussion, hear from former prosecutors as they navigate the turbulent enforcement landscape and forecast future trends.

MODERATORS:

*Briannon Irwin, Senior Managing Consultant, **Berkeley Research Group (BRG)***

*Claire Mackoul, Senior Managing Consultant, **Berkeley Research Group (BRG)***

PANELISTS:

*Craig Carpenito, Partner, Special Matters and Government Investigations, **King & Spalding**; Former U.S. Attorney for the District of New Jersey*

*Andrew Lelling, U.S. Attorney, **U.S. Attorney’s Office for the District of Massachusetts***

*Maurice Bellan, Managing Partner, **Baker McKenzie**; Former Trial Attorney, **U.S. Department of Justice***

3:00-3:45 PM

LIVE **CCO and GC Luminary Panel – Leading Strategies to Advance the Business and Accelerate Innovation**

MODERATOR:

*Mark Scallon, Principal, **Baker Tilly***

PANELISTS:

*Gregory Moss, Executive Vice President, General Counsel and Corporate Secretary, Chief Compliance Officer, **Kadmon***

*Beth Holly, Senior Vice President, Associate General Counsel & Chief Compliance Officer, **Regeneron Pharmaceuticals***

*Rahul Khara, Vice President, Legal and Chief Compliance Officer, **Accelaron Pharma Inc.***

*Jennifer A. Sanfilippo, General Counsel, **Melinta Therapeutics***

4:00-5:00 PM

LIVE **Compliance and Ethics Exchange – Best Practice and Knowledge Sharing Table Talks**

Led by industry colleagues, take part in engaging discussions and timely benchmarking on critical topic areas.

TABLE TALK A

Speaker Programs

MODERATOR:

*Clarissa Crain, Senior Manager, **Deloitte & Touche LLP***

PANELISTS:

*Ernie Hernandez, Vice President and Chief Compliance Officer, **GBT***

*Hannah Putnam, Corporate Ethics & Compliance Officer,
Fresenius Medical Care North America Renal Therapies Group*

*Brian Sharkey, Director, U.S. Commercial Compliance & Ethics,
Teva Pharmaceuticals*

TABLE TALK B

Insights for Emerging and Newly Commercial Companies

MODERATOR:

*Stefanie Doebl, Of Counsel, **Covington and Burling LLP***

PANELISTS:

*Christie Camelio, Chief Compliance, Ethics and Risk Management Officer, **TG Therapeutics***

*Ed Sleeper, Ethics and Compliance Officer, **Esperion Therapeutics, Inc.***

*Amy Wilson, Senior Director, Head of U.S. Compliance, **Morphosys, Inc.***

*Terra Buckley, Vice President, Head of Compliance Advisory Services, **MedPro Systems***

TABLE TALK C

Clinical and R&D Compliance

*Brian Malkin, Partner, **McDermott, Will & Emery LLP***

*Dianne Raccasi, Principal Consultant, **Parexel***

TABLE TALK D

Creative Compliance Training Solutions

*Daniel O’Connor, Senior Vice President, **PharmaCertify by NXLevel Solutions***

*Jackie Parris, Senior Manager, Compliance, **Incyte Corporation***

*Jen Anderson, Associate Director of Training & Communications, **Vertex Pharmaceuticals***

DAY THREE: THURSDAY, APRIL 29, 2021

*Please note all times are listed in EDT

9:30-10:00 AM

LIVE IFPMA Spotlight – Deep Dive into Evolving International Best Practices

Darren Jones, Principal, **Baker Tilly**

Chrisoula Nikidis, Head of Ethics and Compliance, **Takeda Canada**

10:05-10:35 AM

LIVE Hot Topics in HCP Fair Market Value

Paul Silver, Principal, **Deloitte & Touche LLP**

Dominique Donovan, Manager, Regulatory & Compliance Life Sciences, **Deloitte & Touche LLP**

10:40-11:10 AM

LIVE The EU e-Privacy Directive and the Impact on Monitoring Digital Communications and Social Channels

Ryan Smyth, Managing Director, Technology, **FTI Consulting**

Rena Verma, Senior Managing Director, Technology, **FTI Consulting**

11:15 -11:45 AM

LIVE From Surviving to Thriving – How Companies are Adapting Compliance Training Amidst COVID-19

MODERATOR:

Richard Hodgins, CTO, **Intuition Publishing**

PANELISTS:

Julianne Brierley, Director, Head of Compliance Learning, **Novartis**

Melanie Polloway, Executive Director, Compliance, **Daiichi Sankyo, Inc.**

Michael Toohey, Associate Director, Compliance, **Shionogi**

12:00 -1:00 PM

LIVE Diversity and Inclusion Summit

I am intentional. I am accountable. I take action.

Are you ready to lead inclusively? This interactive session will cover a wide range of topics: Where do I start? How can I help my team be more inclusive? What does accountability look and feel like at work? During this one-hour conversation, panelists will share their stories of how they lead themselves, their teams, and within companies. If you are interested in being part of the conversation, don't miss this panel and come ready to share your thoughts and questions on how you take action, be accountable, and lead intentionally with inclusion with self, team and company.

- Work culture that emphasizes the importance of diversity and inclusion
- Policies and procedures designed to change the dynamics of bias and foster equality
- Innovative programs driving empowerment enterprise-wide
- Leadership strategies and lessons learned to advance change

Sujata Dayal, Vice President and Global Chief Compliance Officer, **Medline Industries, Inc**

Veleka Peebles-Dyer, Partner, **Baker McKenzie LLP**

Jim Massey, Sustainability Expert and DEI Champion

Margaret Feltz, Vice President, Ethics and Compliance, **Purdue Pharma L.P.**

1:00 PM

LIVE Close of Virtual Event

IN-DEPTH, ON-DEMAND CONTENT — WHAT YOU WANT. WHEN YOU WANT IT.



There is much to experience and meet about at PCC. On-Demand content is available anytime, to accommodate your needs and schedule.

Compliance Considerations for Interactions with Patient Advocacy Groups

Steve Bychowski, Senior Corporate Counsel, **Sanofi Genzyme**

Jim Flaherty, Senior Vice President and General Counsel, **Rhythm Pharmaceuticals Inc.**

Meena Datta, Partner, **Sidley Austin LLP**

Medical Affairs Compliance

Jeremy Lutsky, Assistant General Counsel, **Myovant Sciences, Inc.**

Veleka Peebles-Dyer, Partner, **Baker McKenzie LLP**

Supply Chain Compliance

Winston Kirton, Partner, **Winston & Strawn LLP**

Kevin Cook, Vice President, Supply Chain North America, **Sandoz**

Hot Topics and Trends for 2021 — New FDA Leadership and Priorities on the Radar

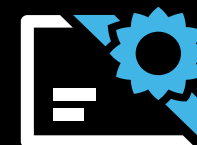
Brian Malkin, Partner, **McDermott, Will & Emery LLP**

Current Good Manufacturing Practices (CGMP) Compliance Issues for Gene Therapy Products

Heath Coats, Principal Consultant, **Parexel**

CONTINUING EDUCATION CREDITS

CPE CREDITS



LEARNING OBJECTIVE:

To provide compliance and legal professionals key updates and industry regulations that impact transparency and aggregate spend reporting processes.

DELIVERY METHOD:

Group Internet-Based

NASBA FIELD OF STUDY:

Specialized Knowledge

PREREQUISITE REQUIREMENTS:

None

PROGRAM LEVEL:

Intermediate

ADVANCE PREPARATION:

None

CANCELLATION BY YOU:

Except as may be otherwise expressly advised as part of the particular Event's registration process, you may cancel your registration in accordance with this Condition: You will receive a refund of your fees paid to Informa (if any) if you cancel your registration 57 days or more before the Event, subject to an administration charge equivalent to 10% of the total amount of your fees plus Taxes (if applicable). The Company regrets that the full amount of your fee remains payable in the event that your cancellation is 56 days or less before the Event or if you fail to attend the Event. If a cancellation changes the entitlement to a multi-registration discount, the lowest value registration will be cancelled first. No cancellations are accepted once any part of a single or multi registration party has accessed the pre-Event networking or partnering facilities, applications or platforms. All cancellations must be sent by email to connect.cancellations@informa.com marked for the attention of Customer Services and must be received by Informa. You acknowledge that the refund of your fees in accordance with Condition 3 is your sole remedy in respect of any cancellation of your registration by you and all other liability is expressly excluded.

PLEASE NOTE:

Speakers and agenda are subject to change. In the event of a speaker cancellation, every effort to find a suitable replacement will be made. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or Informa Connect. AICPA/NASBA guidelines for Continuing Professional Education (CPE) credits are based on a 50-minute credit hour in qualifying NASBA CPE subject areas. One credit equals 50 minutes, and are rounded down to the nearest half-credit. Networking breaks are omitted from the total CPE minutes. This event qualifies for up to 20 CPE credits.

**Events beyond our control include: severe weather conditions, natural and man-made disasters and any other similar events.*

COMPLAINT RESOLUTION POLICY:

For more information regarding refund, complaint and/or program cancellation policies please contact Matt Hannon at 781-462-5356 or email at matt.hannon@informa.com

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***Disclaimer: Agenda is subject to change. Credits are awarded based on participation and are pending approval. Credits are based on session monitoring.*

CLE CREDITS

CLEs are based on a 60-minute hour. Informa Connect is an accredited distance learning provider with PACLE (Pennsylvania CLE Board). Excluding PA, we can issue a certificate that may be used to file with the appropriate MCLE Board(s) or Commission(s). Introductory remarks, unrelated keynotes, business meetings, breaks, receptions, and so on, are not included in the computation of credit. Credit numbers are calculated based on individual participation.

CCB CREDITS

This education activity has been submitted to the Compliance Certification Board (CCB)[®] and is currently pending their review for approval of CCB CEUs.

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IQVIA Commercial Compliance is the industry's trusted name to deliver scalable, end-to-end technology solutions, strategic guidance and best in-class services, to effectively meet the demands of global compliance. Streamline and automate HCP/HCO interactions, efficiently manage global transparency reporting, mitigate risks, reduce costs, increase efficiencies and generate strategic insights from data to improve decision making.



Baker Tilly US, LLP (Baker Tilly) is a leading advisory, tax and assurance firm, providing life sciences, medical device manufacturing, pharmaceutical and omics clients a genuine coast-to-coast and global advantage with critical mass and top-notch talent in major regions of the U.S. and in many of the world's leading financial centers – New York, London, San Francisco, Los Angeles and Chicago. Baker Tilly is an independent member of Baker Tilly International, a worldwide network of independent accounting and business advisory firms in 146 territories, with 36,000 professionals and a combined worldwide revenue of \$3.9 billion. Visit bakertilly.com or join the conversation on LinkedIn, Facebook and Twitter.

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Derek Tagliarino
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Solution Providers, Consultants and Law Firms	\$2199

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Registration & Teams:

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Sr. Professional Development Advisor
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